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EXAMINER
QUAN, ELIZABETH S

ART UNIT	PAPER NUMBER
1743	9

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/867,830	LEHMANN, VOLKER	
	Examiner	Art Unit	
	Elizabeth Quan	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☒ Claim(s) 6 and 10 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 30 May 2001 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement filed 12/17/2002 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

3. The drawings are objected for the following reasons: Reference characters (105) and (404) do not represent structural elements. Reference character (210) has been labeled as both "room" and "space". Reference character (405) has been labeled as the "lower end of a pipette tube" in the specification, but it appears that the arrow for reference character (405) is pointing to liquid or analyte. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: double-sided arrow accompanied by characters "G" and "H" in FIG. 3 and a reference character that resembles IV in FIG. 4. A proposed drawing correction, corrected drawings, or amendment to the specification to

add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the pipette comb, first element, and second element must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

6. Claims 6 and 10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 recites a limitation already incorporated into the last few lines of claim 1. Claim 10 is a method limitation, which does not further limit an apparatus claim.

Specification

7. The abstract of the disclosure is objected to because "Significant Figure 2" appears to be part of the abstract, and its presence is unclear. Correction is required. See MPEP § 608.01(b).

8. The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.

9. The disclosure is objected to because of the following informalities: The list of reference characters should be a part of the specification, and therefore, it should be placed before the page of claims.

Appropriate correction is required.

10. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: pipette comb, first element, and second element.

11. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 3 and 4 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Neither the specification nor drawings disclose a pipette comb let along a first and second element coupled to each other wherein the second element has the pipettes.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

15. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The claim recites elements, such as microtiter plate with a plurality of wells, plurality of pipettes, at least one pump, and analysis chips without structurally connecting them. How are they located in relation to each other?

17. Referring to claim 1, the language renders the claim indefinite. The claim is narrative, disorganized, and confusing. For example line 6 of the claim recites having analysis chips. What element has analysis chips? Does the pump have the analysis chip since the recitation of analysis chip follows immediately from the recitation of pump? Additionally, it should be made more clear that the surface that comes into contact with the analyte is that of the analysis chips. "The surface" as recited in line 8 lacks antecedent basis since it has not been previously recited.

18. Referring to claims 3 and 4, it is unclear what is meant by the pipette comb has first and second element. First of all, the neither the drawings nor specification show a pipette comb, let alone the first and second element of it. Second of all, what a pipette comb "has" is confusing. If an element is attached or somehow connected to the pipette comb, then that element would be part of the pipette comb or the pipette comb has the element. This is the interpretation by which an examination of the claim has been based on.

19. Claim 4 recites the limitation "a plate". There is insufficient antecedent basis for this limitation in the claim. Claim 1 has already recited a microtiter plate.

20. Referring to claims 1 and 6, does the limitation mean the surfaces of some of the analysis chips or some of the surfaces of all the analysis chips comes into contact with the analyte? The wording in this claim is generally narrative and confusing.

21. Referring to claim 8, what is "each case" referring to?

22. Claims 2-9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: The structural connection of the pipette comb with first and second elements, analysis chips arranged in the plate, microtiter plate with 96 or 384 wells, elastic diaphragm, and buffer plate with each other and the elements recited in claim 1. The elements appear to be listed without their relationship with other elements.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,532,805 to Flesher in view of U.S. Patent No. 5,545,531 to Rava et al. or U.S. Patent No. 5,895,631 to Tajima.

Referring to claims 1-8 and 10, Flesher discloses an apparatus addressing liquid analytes in a first embodiment (10) (see FIG. 1; ABSTRACT). The apparatus comprises a plurality of pipettes (20) (see FIG. 1). When the upper ends of the pipettes are clamped against the undersurface of the diaphragm assembly (38) and lower ends of the pipettes are immersed in liquids, valve (52) is operated to reduce pressure through line (54) and in space (56) within manifold structure (34) (see FIG. 1; COL. 2, lines 57-63). Ambient air drawn through the porous material (45,47) partially evacuates each of the cavities, uniformly raising adjacent parts of the membrane into fitting contact within the cavities and drawing liquid samples into the pipettes (see FIG. 1; COL. 2, lines 63-67). To expel the liquid from the pipettes into a second or receiving container-array, replacing a first or supply container-array, the valve is operated to release the partial vacuum in the manifold space, permitting the membrane to snap back (see COL. 3, lines 19-24). Air pressure may be applied through a suitable line (68) to accelerate the snap back (see COL. 3, lines 24-26). The volume of liquid drawn into the tubes depends on the setting of knob (58), which sets the height of the plate (64) and defines the size of the cavity (see COL. 3, lines 4-18).

Alternatively, a second embodiment (200) is like the first embodiment (10) except that there is no cavity-size adjustment (see COL. 3, lines 27-29). Cavity size is a fixed constant (see

COL. 3, lines 29 and 30). The apparatus comprises a plurality of pipettes (220) configured as a pipette comb (280) and a microtiter plate (272) with a plurality of wells (see FIGS. 2-8; COL. 3, lines 31-34; COL. 4, lines 41-45). The pipette comb (280) has a first element (270) and second element (234) coupled to each other by screws (282) (see FIG. 2). The second element (234) has the pipettes when the system is about to draw in or expel sample liquid as the diaphragm assembly becomes attached to the pipettes and draws in liquid or expels liquid from the pipettes. It is noted that it is difficult to differentiate which element belongs to another element when the parts of the system are interconnected and interrelated with each other. The parts of the system have different relationships with each other depending on the functioning mode. For examining purposes, if a first element has a second element, the first element is connected to the second element. The pipette tips are positioned in the wells of the microtiter plate, which is between the first and second elements (see FIGS. 2-8; COL. 4, lines 22-25). The valve (252) is operated to simultaneously draw in or expel sample liquid as desired (see FIGS. 2-8; COL. 4, lines 26 and 27).

Flesher discloses a valve evacuating each of the cavities to draw liquid and releasing the vacuum and/or applying air pressure to permit the membrane to snap back (see FIGS. 1-8; COL. 2, lines 57-67; COL. 3, lines 19-26). All valves have the capability of controlling the amount of pressure or vacuum applied. Flesher doe not explicitly disclose that a vacuum or pressure pump is supplying the vacuum or pressure, which is controlled by the valve, to deform the membrane for drawing or expelling liquids. However, it would have been obvious to one having ordinary skill in the art to provide a vacuum or pressure pump for supplying the vacuum or pressure at any

desired or necessary pressure (i.e. less than an analyte surface tension possibly formed in the pipette) to draw or expel sample liquid since it is very well known and commercially available.

Flesher does not disclose an analysis chip assigned to each well to analyze an analyte. However, Rava et al. disclose an analysis chip assigned to each well to handle multiple samples simultaneously, which would be advantageous when large amounts of information are required quickly (see COL. 1, lines 18-24 and 50-55; COL. 2, lines 1-19 and 54-57; COL. 3, lines 39-67; COL. 4, lines 1-12; COL. 7, lines 56-67; COL. 8, lines 22-27). When the surface of the chip comes into contact with the analyte, molecules contains in the analyte can be fixed on the surface (see COL. 1, lines 18-24 and 50-55; COL. 2, lines 1-19 and 54-57; COL. 3, lines 39-67; COL. 4, lines 1-12; COL. 7, lines 56-67; COL. 8, lines 22-27). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Flesher to provide an analysis chip within each well as in Rava et al. to handle multiple samples simultaneously.

Alternatively, Tajima discloses a chip placed in each sucking or discharging port of a liquid sucking/discharging line of the pipette to execute a sequence of work efficiently and automatically (see COL. 3, lines 50-67; COL. 5, lines 44-51). In a case where a plurality of liquid sucking/discharging lines are provided in parallel, the processing capacity is improved and a multi-channel processing line can be realized (see COL. 44-54). In such a circumstance, since the pipettes are located in the second element of the pipette comb with two elements, chips that are arranged on a plate within the pipette is arranged between the first and second element. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Flescher to provide an analysis chip within each

pipette, which may be assigned to a well of a microtiter plate, as in Tajima to perform a sequence of work efficiently and automatically.

Flesher does not disclose the microtiter plate with 96 or 384 wells. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Flesher to provide a microtiter plate with 96 or 384 wells as it is the very well known and the standard of current industry to use such plates to conform with existing automation. Furthermore, Rava et al. disclose providing biological chips in each well of the microtiter plate with 96 wells arranged in 8 rows and 12 columns.

26. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,532,805 to Flesher in view of U.S. Patent No. 5,545,531 to Rava et al. or U.S. Patent No. 5,895,631 to Tajima. as applied to claims 1-8 and 10 above, and further in view of U.S. Patent No. 5,174,162 to Miyake et al. or U.S. Patent No. 5,171,537 to Wainwright et al.

Referring to claim 9, Flesher in view of Rava et al. or Tajima do not disclose a buffer plate provided for each pipette to mix the analyte delivered by the pipette. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Flesher in view of Rava et al. or Tajima to provide a buffer plate for each pipette for mixing analyte delivered by the pipette as Miyake et al. and Wainwright et al. each disclose that a buffer plate within pipettes mix the analyte delivered by the pipette to provide a uniform mixing concentration, afford high reaction and mixing efficiency, and make washing easy.

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. They include one or more limitations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743

eq

Jill Warden
Supervisory Patent Examiner
Technology Center 1700